



Food and Drug Administration  
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October 31, 2014

New Star Lasers Incorporated  
% Ms. Pamela M. Buckman  
Buckman Company Incorporated  
2800 Pleasant Hill Road, Suite 175  
Pleasant Hill, California 94523

Re: K142286

Trade/Device Name: NS3000™ StoneLight Laser System  
Regulation Number: 21 CFR 878.4810  
Regulation Name: Laser surgical instrument for use in general and  
plastic surgery and in dermatology  
Regulatory Class: Class II  
Product Code: GEX  
Dated: October 4, 2014  
Received: October 7, 2014

Dear Ms. Buckman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

**David Krause -S**

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.  
Director  
Division of Surgical Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K142286

Device Name

NS3000™ StoneLight Laser System

Indications for Use (Describe)

The NS3000 laser system is intended for use in surgical procedures using open, laparoscopic and endoscopic incision, excision, resection, ablation, vaporization, coagulation and hemostasis of soft tissue in use in medical specialties including: Urology, Urinary Lithotripsy, and General Surgery.

Urology: Open and endoscopic surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including: urethral strictures, bladder neck incisions (BNI), ablation and resection of bladder tumors, urethral tumors and ureteral tumors, condylomas, and lesions of external genitalia.

Lithotripsy and Percutaneous Urinary Lithotripsy: Endoscopic fragmentation of urethral, ureteral, bladder and renal calculi, endoscopic fragmentation of kidney calculi, and treatment of distal impacted fragments of steinstrasse when guide wire cannot be passed.

General Surgery: Open, laparoscopic and endoscopic surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including: skin incision, excision of external and internal lesions, complete or partial resection of internal organs, tumors and lesions, and biopsy.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

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## **510(K) SUMMARY**

**K142286**

Submitter: New Star Lasers, Inc.  
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Contact Person: Pamela M. Buckman  
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Summary  
Preparation Date: October 27, 2014

### **II. Names**

Proprietary Name: NS3000™ StoneLight Laser System  
Common Name: Holmium YAG Laser  
Classification Name: Laser surgical instrument for use in  
General/Plastic Surgery and Dermatology  
Reference: 21 CFR Part 878.4810  
Regulatory Class: Class II  
FDA Panel: General and Plastic Surgery  
Product Code: GEX

### **III. Predicate**

NS2500™ Laser System (K132607)

### **IV. Device Description**

The New Star Model NS3000 is a compact, portable, self-contained system that produces a beam of infrared radiation at 2,100 nm wavelength for treatment, and a visible laser diode beam at 532 nm for aiming. The system emits a pulsed laser beam which is delivered to the treatment site using a fiber-optic delivery system. The system consists of a laser console, a fiber-optic delivery system, and a footswitch.

The system provides safety features that are designed to protect the user and patient from high voltages and laser emissions.

The console consists of a control panel, a laser head assembly, a power supply, and a cooling system. It also contains an ON/OFF key switch, Emergency Off switch, External Power Meter connector, Fiber-Optic receptacle, Interlock Jumper plug/receptacle, and a footswitch receptacle. The fiber-optic delivery system includes a linear flash lamp pumped holmium laser cavity and resonator, a 3 milliwatt laser diode, two optical detector assemblies, lenses and cables. The footswitch is used to initiate delivery of laser energy according to preset parameters.

#### V. Summary of Non Clinical Tests

New Star utilized IEC 60601-1-2; EN 61000-3-3 test standards to establish a basis for the determination of equivalence. The NS3000 Holmium Laser System performance characteristics were established by referencing the known performance characteristics of the predicate device. Specifications for the NS2500 Laser System were established to assure that the predicate system and the NS3000 Laser System performed in an equivalent manner. Performance specifications were set utilizing national and international standards for such devices with respect to output, indications for use, safety features and electromagnetic interference where it was established as suitable for the environment of use. All testing was conducted and established that the NS3000 Holmium Laser System met or exceeded its design specifications and performed equally or better than the stated performance of the predicate.

Conclusions drawn from these non-clinical tests demonstrate that the device is as safe, as effective and performs at least as safely and as effectively as the legally marketed device identified in this Summary.

#### VI. Indications for Use

The NS3000 laser system is intended for use in surgical procedures using open, laparoscopic and endoscopic incision, excision, resection, ablation, vaporization, coagulation and hemostasis of soft tissue in use in medical specialties including: Urology, Urinary Lithotripsy, and General Surgery.

Urology: Open and endoscopic surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including: urethral strictures, bladder neck incisions (BNI), ablation and resection of bladder tumors, urethral tumors and ureteral tumors, condylomas, and lesions of external genitalia.

Lithotripsy and Percutaneous Urinary Lithotripsy: Endoscopic fragmentation of urethral, ureteral, bladder and renal calculi, endoscopic fragmentation of kidney calculi, and treatment of distal impacted fragments of steinstrasse when guide wire cannot be passed.

General Surgery: Open, laparoscopic and endoscopic surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including: skin incision, excision of external and internal lesions, complete or partial resection of internal organs, tumors and lesions, and biopsy.

VII. Summary of Technological Characteristics

Technical Characteristics	K033437	K132607 NS2500 New Star Laser (Predicate)	K142286 NS3000 New Star Laser (Modified NS2500)
RoHS-Compliant	No	No	Yes
Keypad	Yes	Yes	Replaced by Touch Screen
Type Of Laser	Pulsed, solid-state Holmium:YAG	Pulsed, solid-state Holmium:YAG	Pulsed, solid-state Holmium:YAG
Pulse Width	150-800 $\mu$ sec	150-800 $\mu$ sec	150-800 $\mu$ sec
Power Output	30W	30W	30W
Aiming Beam	1 mW Green 532 nm or 1 mW Red 635	1 mW Green 532 nm	1 mW Green 532 nm
Beam Delivery	200 $\mu$ m and 273 $\mu$ m fibers	200-1000 $\mu$ m single use; reusable fiber assemblies	150-1000 $\mu$ m single use; reusable fiber assemblies
Exposure Time	Single Pulse; Continuous	Single Pulse; Repeat Pulse; Continuous	Single Pulse; Repeat Pulse; Continuous
Repetition Rate	4-20 Hz	5-20 Hz	5-20 Hz
Energy per Pulse	0.5-4.0 J	0.4 to 2.5 J	0.25 to 3.0 J
Wavelength	2100 nm	2100 nm	2100 nm
Utilities	230 vAC 50/60 Hz; 16A single phase	200/208/220/230/240 vAC, 50/60 Hz, 10A single phase	200/208/220/230/240 vAC, 50/60 Hz, 10A single phase

VIII. Rationale for Substantial Equivalence

The NS3000 Holmium Laser System shares the same indications for use, device operation, overall technical and functional capabilities, and therefore is substantially equivalent to the predicate device (K132607, and its predicate K033437). The minor modifications to the predicate device do not represent substantive changes to the technical, functional or operational capabilities.

IX. Safety and Effectiveness Information

The review of the indications for use and technical characteristics demonstrates that the NS3000 Laser System is substantially equivalent to the

predicate device. The modifications to the NS2500 are minor and no new safety or effectiveness questions are applicable.

X. Conclusion

The NS3000 Laser System was found to be substantially equivalent to the predicate device. The NS3000 Laser System shares the same indications for use, similar design features, and functional features with, and thus is substantially equivalent to the predicate device.